

Business Model Canvas *for Medical Devices*

Guide Book

This model is based on both the business model canvas and lean canvas, but it has been modified to focus on medical devices. Its purpose is to assist inventors and/or entrepreneurs in evaluating the commercial potential of, or outlining a commercial pathway for, their medical devices.

How to use

- Read this manual and review the canvas.
- Fill out each section with bullet points. Keep each bullet to a few words – no more than 1 sentence. Be sure to answer the questions, where applicable, outlined in this guide.
- Begin in the customer section – everything flows from here.

Each bullet point will essentially be a hypothesis that will need validation. This model will help you think about the most important aspects of commercializing a medical device. It will help you to prove your device represents a significant opportunity that should be pursued.

Please note that this canvas is NOT a static document. As you work to validate each hypothesis, you will update your canvas based on new information. Having a validated business canvas will help to reduce a significant amount of early risk associated with medical device start-ups.

THE OPPORTUNITY

This section outlines the basic business case. You will identify why your product has value and why end users will purchase it instead of alternative solutions.

Problem

This is all about defining what the problem is with the current standard of care. Your bullets should list specific problems that your solution, or product, will solve.

Solution

What is your solution? What features are key to making this solution a success? Make sure your bullets address the problem bullets, but more can be included.

Value Proposition

These bullets should outline, very simply, why this solution is different/better than the current standard of care. A medical product's value proposition should also include an explanation of how it will lower healthcare cost and improve care. These are important elements of success, so separate boxes are provided.

- **Lower Cost Case**

Most healthcare settings are cost sensitive, some more than others. Developing a case for how this product/solution reduces the cost of care can therefore be an essential element of success. This case can be made on a per patient basis, or within a larger context for the healthcare setting (think cheaper than alternative solutions vs. reducing re-admittance rates).

- **Lower Cost & Improve Care Case**

Improving care should be straight forward – we're talking about how your product will improve patient outcomes.

Initial and Ultimate Market

What is the ultimate market size for this product? Where will you start and why?

The Customer

Healthcare is a tricky market that can be highly segmented. There are multiple settings of care, which can dictate who uses your product, how cost sensitive they are, who the payers are and more. The following section will give you a little more insight into your market.

Healthcare Setting:

There are many settings in healthcare. Hospitals, nursing homes and long-term care facilities, ambulatory care centers, physician's offices, home healthcare, rehabilitation centers and more. Identifying what setting(s) of care your product will be used in, or which you will be targeting first, is important. In this section, bullet each setting of care your product would be used in.

**** Write each setting of care in a different color. Go through the canvas and fill it out based on that setting of care alone – using the same color. You will likely find different settings of care result in different answers. Having different colors will help to organize your thoughts. This will also help you understand what settings of care will be the best initial target. ****

End User

Who will be the end user(s) for your product? Take the time to think about all the people involved with use of the product. This will be important as you think about how you produce impacts the current standard of care.

Decision Maker

Typically, in medical settings, the end user is not the purchaser/ decision maker. Who makes purchasing decisions in the healthcare setting(s) you are targeting?

Payer

Who pays for your product? Does it need a reimbursement code or is it part of a bundled payment? What code exists and what is the typical payment? How will you get your produce reimbursed? All these questions are important and you need to know them BEFORE you head down any regulatory pathway.

The Risk

Regulation

Who regulates this product? What is the intended use of the product? What is the regulatory pathway?

Intellectual Property

Is your product protected? Do you have freedom to operate? How difficult is it to create “around” this intellectual property? How long do you have left on your patent(s)?

Current Standard of Care Challenges

What is currently used to solve the problem? How is it used, and who uses it in standard procedures? Take the time to think about all the people involved with use of your product. Will your solution change what people do during the procedure? Will it add or save time?

Key Partners

What partnerships will you need? Think reimbursement and regulation guidance, manufacturing, distribution networks and sales teams. Do you have these contacts or do you still need them?

The Economics

Milestones/Timeline

List out the major steps on your commercial pathway. Think about product development and the clinical work you will need to do for regulatory approval. Don't forget to outline finding distribution partners and initial sales.

Cost Estimates

Developing and launching a medical device is not cheap. What are your major costs? Based on the major milestones you listed, outline your costs. How much do you think it will take you to get to initial sales? What do you need in your initial round of investment?

Revenue Potential

What is the unit cost of your product and what will it sell for? What companies would be most interested acquisition if it were successful? What stage of sales do acquisitions in this area take place?